IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC SCIMED, INC. and BOSTON SCIENTIFIC CORPORATION, Plaintiffs, v. CORDIS CORPORATION and JOHNSON & JOHNSON, INC., Defendants.	)	Civ. No. 03-283-SLR
BOSTON SCIENTIFIC SCIMED, INC. and BOSTON SCIENTIFIC CORPORATION, Plaintiffs, v. CORDIS CORPORATION, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, JOHNSON & JOHNSON, INC., and ADVANCED CARDIOVASCULAR SYSTEMS, INC., Defendants.	)	Civ. No. 03-1138-SLR

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MEMORANDUM OPINION

Dated: October 14, 2005
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Incorporated (collectively "BSC") filed this action against defendants Cordis Corporation, Johnson & Johnson, Incorporated, Guidant Corporation, Guidant Sales Corporation, and Advanced Cardiovascular Systems, Inc. (collectively "Cordis") alleging Cordis' Cypher stent infringes claims 33 and 40 of U.S. Patent No. 6,251,920 ("the '920 patent").

Pending before the court are Cordis' motions for summary judgment. (C.A. No. 03-283-SLR, D.I. 374, 376) On August 18, 2005, the court heard oral arguments on these motions. The court has jurisdiction over these matters pursuant to 28 U.S.C. § 1338.

II. BACKGROUND

The '920 patent generally relates to a method for treating or preventing cardiovascular pathologies by administration of a therapeutic agent. One of the original applications, Application PCT/US92/08220 ("the '08220 application"), was filed on September 25, 1992. That application was abandoned. On January 28, 1993, Application Number 08/011,669 ("the '669 application") was filed as a continuation-in-part of the '08220 application and subsequently abandoned. Application Number 08/062,451 ("the '451 application"), filed May 13, 1993 as a continuation-in-part of the '669 application, also was later abandoned. On May 12, 1994, Application Number 08/241,844 ("the '844 application") was filed

as a continuation-in-part of the '451 patent and subsequently abandoned. On May 21, 1998, Application Number 09/082,643 ("the '643 application"), which led to the '920 patent, was filed as a continuation-in-part of the '844 application. The '08220 application, '669 application, '451 application and '844 application are incorporated by reference into the '920 patent. ('920 patent, col. 1, ll. 11-18)

The other original application, Application Number 08/061,714 ("the '714 application"), was filed May 13, 1993. That application was abandoned. On May 12, 1994, Application Number 08/242,161 ("the '161 application", now U.S. Pat. No. 5,847,007) was filed as a continuation-in-part of the '714 application. Application Number 08/486,334 ("the '334 application", now U.S. Pat. No. 5,770,609) was filed on June 7, 1995 as a continuation-in-part of the '161 application. The '643 application, which led to the '920 patent, is a division of the '334 application. The '714 application, '161 application, and '334 application are incorporated by reference into the '920 patent. ('920 patent, col. 1, ll. 5-11)

Claim 40[1] of the '920 patent depends from claim 33[2] and discloses localized administration of the therapeutic agent at a site of vascular trauma. The court has construed the disputed limitations of these claims in an order which has issued concurrently with this memorandum opinion.

The accused device, the Cypher stent, is a drug-eluting Bx Velocity balloon expandable stent.

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec.

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[1]Claim 40 states: "The method of claim 33 wherein the administration is localized at a site of vascular trauma." ('920 patent, col. 62, ll. 13-14)

[2]Claim 33 reads:

> A therapeutic method for preventing or treating a cardiovascular indication characterized by a decreased lumen diameter comprising administering to a mammal at risk of or afflicted with said cardiovascular indication, a cytostatic dose of a therapeutic agent, wherein the cytostatic dose is effective to increase the level of TGF-beta so as to inhibit smooth muscle cell proliferation, inhibit lipid accumulation, plaque stability, or any combination thereof.

('920 patent, col. 60, ll. 58-65)

Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury to reasonably find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. Cordis' Motion For Summary Judgment That Claims 33 and 40 of the '920 Patent Are Invalid Under 35 U.S.C. § 112

Cordis argues that claims 33 and 40 of the '920 patent are invalid under 35 U.S.C. § 112 for three reasons. First, Cordis posits that the asserted claims are indefinite because they omit essential claim language. Second, Cordis contends that the specification does not enable the asserted claims because it does not provide sufficient teaching for one of skill in the art to practice the claimed invention without undue experimentation. Finally, Cordis argues that the specification does not provide an adequate description of the claimed invention so as to demonstrate that the inventors were in possession of the full scope of the claims.

A patent is presumed valid and the burden of proving invalidity, whether under § 112 or otherwise, rests with the challenger. See 35 U.S.C. § 282. In order to overcome this presumption, the party challenging validity bears the burden of proving by clear and convincing evidence that the invention fails to meet the requirements of patentability. See Hewlett-Packard Co. v. Bausch & Lomb, 909 F.2d 1464, 1467 (Fed. Cir. 1990). Clear and convincing evidence is evidence that "could place in the ultimate factfinder an abiding conviction that the truth of

[the] factual contentions are 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

1. Indefiniteness

A patent specification shall conclude with one or more claims that "particularly [point] out and distinctly [claim] subject matter which the applicant regards as his invention." 35 U.S.C. § 112, P 2 (2003). "A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Personalized Media Communs., L.L.C. v. ITC, 161 F.3d 696, 705 (Fed. Cir. 1998).

The only assertion of indefiniteness by Cordis is that the effect on plaque stability as described in claim 33 of the '920 patent is indeterminate. As construed by the court, the claim limitation "inhibit smooth muscle cell proliferation, inhibit lipid accumulation, plaque stability, or any combination thereof" means "inhibit smooth muscle cell proliferation, inhibit lipid accumulation, **increase** plaque stability, or any combination thereof." (Emphasis added) The specification discusses increasing plaque stability. ('920 patent, col. 2, ll. 55-59) A preferred embodiment specifically discusses stabilization of an arterial lesion associated with artherosclerosis by use of a formula which "increases plaque stability." ('920 patent, , col. 3, ll. 33-40) The prosecution history makes reference to

"increasing" plaque stability. (C.A. No. 03-283-SLR, D.I. 382, Ex. 11 at BSX 388274; C.A. No. 03-283-SLR, D.I. 382, Ex. 11 at BSX 388277, BSX 388155) Thus, the court finds that "inhibit smooth muscle cell proliferation, inhibit lipid accumulation, plaque stability, or any combination thereof" has a discernable meaning that would be understood by one of ordinary skill in the art. For this reason, no indefiniteness is present with regard to the asserted claims.

2. Enablement

Under the enablement requirement, a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. See In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). As apparent from § 112, a patent specification is required to contain a disclosure, either through illustrative examples or written description, that is sufficient to teach one skilled in the art how to make and use the invention as broadly as it is claimed. Id. "It is not necessary that a patent applicant test all the embodiments of his invention; what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims." Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (internal citation omitted); accord In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) ("It is well settled that patent

applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art."). Furthermore, a patent need not teach, and preferably omits, that which is well known in the art. See Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1345 (Fed. Cir. 2000), citing Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986). The Federal Circuit has explained that "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. . . . Tossing out the mere germ of an idea does not constitute enabling disclosure." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The enablement requirement is a question of law based on underlying factual inquiries. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); see also, In re Goodman, 11 F.3d 1046, 1049-50 (Fed. Cir. 1993); B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1582 (Fed. Cir. 1996).

In support of its argument of non-enablement, Cordis initially asserts that the inventors of the '920 patent have made the mistake of attempting to claim a genus while disclosing only a limited number of species in that genus. Cordis further claims that the '920 patent does no more than describe the intended result of a potential therapeutic agent, thus leading to the need for undue experimentation. In response, BSC argues that the '984

patent disclosure is enabling, based on expert opinions and the available technology and level of ordinary skill at the time of the patent application.

Cordis maintains that the patent does not enable one skilled in the art to practice the full scope of the claimed invention without undue experimentation. While asserting that undue experimentation would be necessary to make and use the claimed invention, no evidence is presented by Cordis which sufficiently proves that someone skilled in the art would be unable to practice claim 33 or claim 44 by using the disclosures of the '920 patent. Cordis argues that BSC's claims are directed to a broad genus which is described only functionally such that the characteristics of the specific agents within the genus cannot be determined. However, the specification of the '920 patent describes two specific substances that possess the desired characteristics for use with the invention, and an assay is described which is directed to allowing one skilled in the art to determine additional substances for use in practicing the invention. (C.A. No. 03-283-SLR, D.I. 404, ex. 1, col. 25, l. 47 - col. 31, l. 27; col. 45, l. 65 - col. 46, l. 2)

The fact that experimentation using the specified assay may be necessary to practice the invention is not fatal to meeting the enablement requirement. A disclosure may be enabling even though a considerable amount of routine experimentation is

required to practice the invention. See PPG Indus. Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996); see also Telectronics, Inc., 857 F.2d at 785. The fact that some experimentation is necessary does not preclude enablement as long as the amount of experimentation is reasonable given the nature of the invention and the state of the art. See In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). If "undue" experimentation is required to make and use the invention, however, the patent fails to satisfy the enablement requirement. See PPG Indus., Inc., 75 F.3d at 1563-65.

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. . . . Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d at 737 (internal citations and footnotes omitted) (quoting In re Jackson, 217 U.S.P.Q. 804, 807 (Pat & Tr.

Office Bd. App. 1982)). Cordis has not specifically discussed any of the "Wands factors" and, while asserting that experimentation would be needed to practice the claimed invention, has failed to show that any such experimentation would be undue.

In continuing its non-enablement argument, Cordis has offered evidence to suggest that the assays and compounds described in the '920 patent are not effective for their claimed use. Specifically, Cordis offered expert opinion evidence suggesting that the specific compounds disclosed - heparin and tamoxifen - are unrelated to each other and are functionally deficient for use with the claimed invention such that their mention in the specification does not enable one to make and use the claimed invention. (C.A. No. 03-283-SLR, D.I. 379, ex. 42 at 110:15-17; ex. 46 at 35:3-23) However, BSC has offered evidence suggesting that the assay and compounds are appropriate and would allow the invention to be practiced by one skilled in the art as claimed. (C.A. No. 03-283-SLR, D.I. 404, ex. 1, col. 45, l. 65 - col. 46, l. 2; C.A. No. 03-283-SLR, D.I. 405, ex. 55 at 86) As a result, the court finds that there are genuine issues of material fact for trial with respect to the particular efficacy of heparin and tamoxifen for use with the claimed invention.

Finally, Cordis contends that evidence suggesting the failure of the inventors and others in the scientific community

to practice the claimed invention supports a finding of non-enablement. BSC counters with evidence that the therapeutic agent studies which were included as examples in the specification are proof that the claimed invention works. In light of the evidence presented, the precise effectiveness of the claimed invention is not clear and remains an issue for resolution at trial.

The court concludes that there exist genuine issues of material fact as to whether the '920 patent is invalid for failure to comply with the enablement requirement and, therefore, shall deny Cordis' motion for summary judgment on this issue.

3. Written Description

The statutory basis for the written description requirement is found in 35 U.S.C. § 112, paragraph 1, which provides in relevant part:

> The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

The written description requirement is separate and distinct from the enablement requirement. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). The written description requirement is "broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he

or she was in possession **of the invention**." Id. (emphasis in original). In other words, a patent must "'clearly allow persons of ordinary skill in the art to recognize that [the patentee] invented what is claimed.'" In re Alton, 76 F.3d 1168, 1172 (Fed. Cir. 1996) (quoting In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). A challenger must provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention. See id. 76 F.3d at 1175.

Cordis argues that the specification does not adequately describe the claimed invention so as to show that the inventors were in possession of the full scope of the claims. BSC contends that the level of detail contained in the specification of the '920 patent makes it clear that the full scope of the claims were possessed by the inventors.

In beginning its argument for invalidity based on lack of written description, Cordis asserts that the description of an assay for determining whether a compound performs a specific function does not describe claims to all compounds that possess that function. While that argument is consistent with the Federal Circuit holding in Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004), its reasoning does not take into account all of the facts before this court. Here, the '920 patent has disclosed specific compounds which could be used

in the claimed method, in addition to an assay which is purported to detect other compounds possessing the desired function. Cordis has failed to show by clear and convincing evidence that the disclosure of specific compounds for use with the claimed invention constitutes inadequate written description of the invention.

As mentioned under the enablement discussion above, Cordis offered evidence suggesting that heparin and tamoxifen do not work effectively as therapeutic agents for use with the claimed invention. Cordis offered this evidence as proof that the inventors of the '920 patent did not possess the full scope of the claimed invention. However, both expert reports and the studies using tamoxifen and heparin which were cited in the specification of the '920 patent provide contrary evidence which supports BSC's contention that the inventors did, in fact, possess the full scope of the invention.

The court concludes that there exist genuine issues of material fact regarding whether the '920 patent is invalid for failure to comply with the written description requirement and, therefore, shall deny Cordis' motion for summary judgment on this issue.

B. Cordis' Motion For Summary Judgment That the Cypher Stent Does Not Infringe Claims 33 and 40 of the '920 Patent

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). A court should employ a two-step analysis in making an infringement determination. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the asserted claims to ascertain their meaning and scope. Id. Construction of the claims is a question of law subject to de novo review. See Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998). The trier of fact must then compare the properly construed claims with the accused infringing product. Markman, 52 F.3d at 976. This second step is a question of fact. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). Literal infringement occurs where each limitation of at least one claim of the patent is found exactly in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987). An accused product that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused product either literally or equivalently. See Sextant Avionique, S.A. v. Analog Devices, Inc., 172 F.3d 817, 826 (Fed. Cir. 1999). The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v.

Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

Cordis asserts that BSC cannot successfully argue infringement since it has failed to meet its burden of proof regarding the elements of the accused product. As construed by the court, claims 33 and 40 of the '920 patent require the administration of a cytostatic dose of a therapeutic agent effective to increase the level of active TGF-beta so as to inhibit smooth muscle cell proliferation, inhibit lipid accumulation, increase plaque stability or any combination thereof. According to Cordis, BSC has failed to show that the dose of rapamycin eluted by the Cypher stent is "effective to increase the level of TGF-beta" and that the increased level of TGF-beta is effective to "inhibit smooth muscle cell proliferation." Specifically, Cordis alleges that: (1) BSC has failed to present any evidence that the Cypher stent infringes claims 33 and 40 of the '920 patent; and (2) BSC has failed to conduct any experiments in support of its unproven hypothesis of infringement.

Cordis first argues that BSC has offered no evidence that the Cypher stent increases the level of TGF-beta. Cordis maintains that BSC's infringement accusations are based solely on the unproven hypothesis of expert Dr. Leslie Benet, whom Cordis claims: (1) admits that he has conducted no tests in support of

his hypothesis; (2) is unaware of any articles of publications which show that rapamycin eluted by the Cypher stent increases TGF-beta levels; (3) provides no link between TGF-beta and the inhibition of human smooth muscle cell growth; and (4) admits that he is not aware of any studies by BSC or others which show that rapamycin eluted by the Cypher stent increases TGF-beta levels. Cordis offers evidence from its deposition of Dr. Benet which supports these claims. (C.A. No. 03-283-SLR, D.I. 424, ex. 58 at 61:24-63:2, 125:8-126:16, 128:15-129:8)

In responding to Cordis' argument, BSC points to the expert report of Dr. Benet, which cites to articles from scientific literature suggesting that TGF-beta inhibits the proliferation of human and animal smooth muscle cells and that a biochemical mechanism exists whereby rapamycin elevates TGF-beta levels to inhibit vascular smooth muscle cell proliferation. (C.A. No. 03-283-SLR, D.I. 404, ex. 3 at ¶¶ 22-39) BSC also defends its reliance on Dr. Benet's opinion by noting that his conclusion is supported by the testimony of Cordis' expert, Dr. Nigel Buller, who stated that the rapamycin delivered by the Cypher stent is in a cytostatic dose designed to inhibit smooth muscle cell proliferation. (C.A. No. 03-283-SLR, D.I. 405, ex. 53 at 127:7-13, 129:20-130:3)

The parties agree that the Federal Circuit requires an expert to set forth the factual foundation for his opinion in

sufficient detail for the court to determine whether the factual foundation would support a finding of infringement. Novartis Corp. v. Ben Venue Laboratories, Inc., 271 F.3d 1043, 1054 (Fed. Cir. 2001). The court finds that the expert report of Dr. Benet, detailing the evidence and reasoning used to reach his conclusion, provides a sufficient foundation to support a finding of infringement. Due to the evidence cited in support of the hypothesis of Dr. Benet, the court finds that there are genuine issues of material fact for trial with respect to the effect of rapamycin on TGF-beta levels. Thus, Cordis' motion for summary judgment cannot be granted on this sub-issue.

Cordis continues its non-infringement argument by claiming that BSC has failed to conduct any experiments to substantiate its unproven hypothesis of infringement. Cordis suggests that the failure of BSC to conduct the "key test" detailed in the '920 patent, which would purportedly determine whether rapamycin inhibits vascular smooth muscle cell proliferation as a result of an increase in the level of TGF-beta, is proof of the speculative nature of BSC's claim of infringement.

As BSC has correctly noted, there is no requirement for an expert to perform or rely on testing of an accused product in order to establish infringement. Allen Archery, Inc. v. Browning Mfg. Co., 819 F.2d 1087 (Fed. Cir. 1987). While the results of the "key test" to evaluate rapamycin would be informative to the

court on the issue of infringement, even in the absence of such evidence, there exist issues of fact which prevent the court from granting summary judgment of non-infringement. First, the parties acknowledge that rapamycin can be used as a cytostatic agent and that the Cypher stent may deliver a cytostatic dose of rapamycin which inhibits vascular smooth muscle cell proliferation. (C.A. No. 03-283-SLR, D.I. 423 at 3-4; C.A. No. 03-283-SLR, D.I. 405, ex. 53 at 127:7-13, 129:30-130:3) Whether rapamycin causes an increase in the amount of active TGF-beta in effecting this result is a genuine issue in contention. Secondly, the evidence offered by Cordis that rapamycin does not increase TGF-beta levels in vascular smooth muscle cells does not suggest whether rapamycin increases TGF-beta levels outside of vascular smooth muscle cells. If such an increase in TGF-beta levels occurs, evidence has been cited to suggest it may then inhibit vascular smooth muscle cell proliferation. (C.A. No. 03-283-SLR, D.I. 405, ex. 55 at 60:15-24) This is another issue, material to the court's infringement analysis, which remains in contention.

The court concludes that there exist genuine issues of material fact regarding whether the Cypher stent infringes claims 33 and 40 of the '920 patent and, therefore, shall deny Cordis' motion for summary judgment on this issue.

V. CONCLUSION

For the reasons stated, Cordis' motion for summary judgment that claims 33 and 40 of the '920 patent are invalid under 35 U.S.C. § 112 is denied, and Cordis' motion for summary judgment that the Cypher stent does not infringe claims 33 and 40 of the '920 patent is denied. An order consistent with this memorandum opinion shall issue.